REMARKS

Claims 1-6, 10-22, 24-26, 28-29 and 34-35 are pending in the application. Claims 30, 32 and 33 correspond to unelected species. Claim 23 was withdrawn from further consideration by the Examiner in the Office Action mailed 12 November 2008. Claims 7-9, 27 and 31 are cancelled in the present response. Claim 1 has been amended. Claims 34 and 35 are new.

Support for Claim Amendments

Claim 1 has been amended to specify that the cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity. Basis for this amendment can be found in original Claim 8, now cancelled. Claim 1 has been further amended to specify that the the flexible component is free to move laterally and rotationally within the cavity. Basis for this further amendment can be found in original Claim 31, now cancelled.

Claim 34 has been added. New claim 34 finds basis in original claims 1, 10 and 31.

Claim 35 has been added. New claim 35 finds basis in original claims 1 and 8.

Restriction of Claim 23

Claim 23 has been withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species 2 shown in Figure 18 as for having a hinge, and there being no allowable generic or linking claim. Applicants reserve the right to prosecute Claim 23, or any other nonelected claim, in this or any other subsequent related patent application.

Amendment to the Specification

The Examiner objected that the title was not descriptive. The title has now been changed to "Implantable Replacement Joint".

37 CFR 1.83(a) Objection to the Drawings

The Examiner objected that the textured outer surface consisting of screw threads, annular ridges, semi-annular ridges, and expansion fins must be shown or these features cancelled from the claims. Claim 7 has consequently been cancelled, rendering the objection to the drawings moot.

35 USC 112 Claim Rejections

Claim 27 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 27 has consequently been cancelled.

35 U.S.C. § 102 Rejection: Claims 1-5, 8-12, 14-22 and 31 (Fixel)

Claims 1-5, 8-12, 14-22 and 31 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,990,116 (Fixel). Claims 8, 9 and 31 have been canceled. Applicants traverse the rejection of Claims 1-5, 10-12 and 14-22 because Fixel fails to disclose each and every element recited in the claims.

1. Flexible component is free to move laterally and rotationally

Claim 1 has now been amended to specify that the flexible component is free to move laterally and rotationally within the cavity.

Basis for the flexible component being free to move laterally and rotationally within the cavity comes from original Claim 31. The Examiner stated that Claim 31 was anticipated by Fixel, but this statement was not supported by any reasons. The Applicants respectfully submit that original Claim 31 is not anticipated by Fixel, for the following reasons.

Fixel's flexible component is a plurality of individual leaf springs 18 that are stacked up against each other (see Figs 1, 2 and 5). The stack of leaf springs 18 has a rectangular cross-section. The leaf springs 18 sit in cavities 15, 16 formed in the support members 11, 12. The cavities 15, 16 are also rectangular and are sized so that the leaf springs 18 fit snugly within the cavities 15, 16 in a close fit. The rectangular cross

sections of both the leaf springs and the cavities are shown particularly well by the dotted lines in Fig 5, in addition to being apparent from Figs 1 and 2.

Hence, there is actually no possibility of rotational movement, because the rectangular stack of leaf springs cannot be rotated in a rectangular aperture of the same size as the leaf springs. Further, there is also no possibility of lateral movement, because there is no space between the sides of the cavities 15, 16 and the leaf springs 18.

Therefore, Fixel's flexible component is not free to move either laterally OR rotationally within the cavity.

2. The cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity

Claim 1 has also been amended to specify that the cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity.

The effect of this feature is that, in the present invention, the flexible component does not bear any significant axial loads. Instead, axial loads are transferred from the first component to the second component, substantially bypassing the flexible component. In contrast, Figs 1 and 2 of Fixel show a considerable gap between the support members 11, 12 and the flexible component (leaf springs 18) spanning the gap. Thus, Fixel's cavity formed by the bores in the support members 11, 12 is shorter than the stack of leaf springs 18. Therefore, in contrast to the present invention, Fixel's flexible component does indeed bear significant axial loads.

Furthermore, column 3, lines 25 to 28 confirms that the spring assembly 17 (the leaf springs 18) are to be considered as a cantilever beam of a length confined to the short distance between support members 11 and 12. Hence, this is positive, literal confirmation that the support members 11, 12 are not in direct contact with each other. In use, as shown in Figs 1 and 2, there is a gap between the support members 11, 12. This gap would not exist if the cavity was longer than the stack of leaf springs 18, because in that case, the support member 11 would slide down over the leaf springs 18, concealing

them within the cavity. This is not shown in Figs 1 and 2. Therefore, the cavity formed by the bores in the support member 11, 12 is shorter than the stack of leaf springs 18. Hence, the only way that axial loading can pass from the support member 11 to the support member 12 is via the leaf springs 18. Specifically, a load on the support member 11 pushes the upper end of the cavity 15 down on the leaf springs 18, which in turn push on the lower end of the cavity 16 to transfer the axial load to the support member 12. Thus, it is unambiguously clear that Fixel's cavity is actually shorter than Fixel's flexible component (the stack of leaf springs 18) and that Fixel's flexible component is load-bearing in respect of axial loads.

Thus, amended claim 1 is novel over Fixel for the following three reasons:

1) Fixel's cavity is shorter than Fixel's flexible component;

2) Fixel's flexible component is not free to move laterally within the cavity; and

3) Fixel's flexible component is not free to move rotationally within the cavity.

Accordingly, for at least the foregoing reasons, Applicants respectfully request that the rejection of Claims 1-5, 10-12 and 14-22 as anticipated by Fixel be withdrawn.

35 U.S.C. § 103 Rejections:

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Fixel in view of U.S. Patent No. 5,683,466 (Vitale). Claims 24-29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Fixel in view of U.S. Patent No. 5,702,472 (Huebner). Applicants traverse these rejections because the claimed invention cannot be achieved by combining the teachings of Fixel, Vitale and Huebner in any manner.

1. The flexible component being free to move axially, laterally and rotationally within the cavity

In the present invention, the flexible component being free to move axially, laterally and rotationally within the cavity allows the pivot axis (around which the first and second components move relative to one another) to be movable relative to the

device, thereby creating a "sloppy hinge" between the first and second components, as disclosed at page 7, lines 20 to 31 of the application as filed. This permits the first and second components to move axially relative to one another while moving in relative rotation and flexion/extension or in medial/lateral directions. The ability to move axially while rotating, deviating laterally, and flexing or extending enables the replacement joint to move in a similar fashion to the natural joint it is replacing.

In contrast, Fixel is concerned with knee and finger joints (see column 1, lines 6 to 11). Natural knee and finger joints move principally in one plane (forwards and backwards between a bent position and a stretched position). However, natural finger and knee joints also permit very subtle lateral and rotational movements of around 2 to 5 degrees. Fixel's joint is fixed, both laterally and rotationally. The support member 11 is fixed in rotation with respect to the leaf springs 18, which is fixed in rotation with respect to the support member 12 by the snug interference fit of the leaf springs 18 in the cavities 15, 16. Hence, absolutely no rotation is permitted by Fixel. Thus, the subtle rotational movements of the natural finger joint cannot be achieved by Fixel. Furthermore, leaf springs, by definition, allow bending only forwards and backwards and in no other direction. Hence, by the choice of leaf springs, it is impossible for Fixel's device to bend in two directions simultaneously to mimic a natural joint.

Yet another advantage of axial, lateral and rotational freedom of movement is that, with the present invention, the flexible component does not always move in response to relative pivoting of the first and second components, and when it does bend, it does not bend as much as the first and second components. This will now be explained. Since the flexible component has axial, lateral and rotational clearance, small movements of the first and second component do not cause the walls of the first and second components even to contact the flexible component. Therefore, the flexible component is not put under either stress or tension when subtle movements of the first and second component occur.

When large movements occur, again because of the clearance, the flexible component bends through a smaller angle than the first and second components. For example, the first component might pivot at 60 degrees with respect to the second

component, but this may only cause the flexible component to bend at 50 degrees. Please see the enclosed drawing, attached hereto as Exhibit A, which illustrates this difference in bending effect on the flexible component compared to the first and second components. Please note that the clearances in the drawing have been exaggerated for the purposes of this explanation. In contrast, with Fixel, every single movement of the support members 11, 12 relative to each other MUST trigger bending of the stack of leaf springs 18, because there is no axial, lateral or rotational clearance. Furthermore, when the support members 11, 12 pivot through 60 degrees, the leaf springs 18 must also pivot through 60 degrees.

Hence, due to the freedom of movement axially, laterally and rotationally, the flexible component of the present invention undergoes less movement than Fixel's stack of leaf springs, and when it does move, it is bent through a smaller angle. This is an advantage because the flexible component of the present invention undergoes less wear, and therefore has increased longevity.

However, the person of ordinary skill in the art, wishing to improve Fixel's device would never wish to modify Fixel's device such that the stack of leaf springs 18 could move axially, laterally and rotationally within the cavities 15, 16.

The stack of leaf springs 18 has to work together, with each spring being aligned with its neighbours. However, if there was excess room in the cavity for lateral movement or rotation, the stack of leaf springs 18 would cease to be an integrated stack, since some would protrude to the left and right. This could then cause irregular deformation of the springs. Given sufficient room, some of the leaf springs could even come out of the stack completely.

Hence, amended claim 1 is non-obvious over Fixel, because the skilled person would immediately see that modifying Fixel's device such that the stack of leaf springs 18 could move axially, laterally and rotationally within the cavities 15, 16 could never work in the context of Fixel's device.

2. The cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity

The cavity, being longer than the flexible component so that the flexible component can move axially within the cavity, causes the flexible component to be non-load bearing in respect of axial loads. This has two advantages: (1) the flexible component will not wear out so quickly; and (2) the flexible component is protected from being damaged by the cut bone ends.

Considering the first advantage, the Fixel design involves direct axial loading on the flexible component. Joints of the human body undergo high forces, which are created by muscles pulling on tendons. These forces can be of the order of several hundred Newtons. A typical force for gripping an article might be in the order of 200 Newtons. In Fixel, all of this high loading is taken by the stack of leaf springs 18. This is the reason why Fixel relies on a whole stack of springs instead of just a single spring; as column 3, lines 40 to 43 explain that there is no single point of stress or fatigue in the individual leaves and the tension forces are distributed and diffused throughout the total system.

The person of ordinary skill, wishing to improve the strength/life span of Fixel's replacement joint, might find it obvious to add some more leaf springs to the stack, or to form the leaf springs from an even stronger material. However, there is no hint or teaching to redesign Fixel such that the leaf springs 18 are no longer load-bearing, or so that the cavity is longer than the leaf springs.

Considering the second advantage, in order to insert any replacement joint into a human body, a surgeon needs to cut out the damaged bone surfaces as a first step. This exposes freshly cut bone edges. The surgeon then installs the replacement joint. This is true for both the replacement joint of the present invention, and of the joints of Fixel, Vitale and Huebner.

After the surgery, when the patient moves the replacement joint in their normal life, the flexible component can come into contact with the sharp bone edges which were cut by the surgeon, and this abrades or otherwise damages the flexible component.

However, the person of ordinary skill in the art would never seek to modify Fixel, such that the cavity was made longer than the flexible component, because the leaf springs 18 in Figs 1 and 2 of Fixel are the ONLY means of carrying axial loads between the first and second support members 11, 12. Column 3 lines 3 to 43 describes the principle that the stack of leaf springs 18 works as a cantilever beam, bridging the joint and thereby spacing the support members 11, 12 apart. As shown in Figs 1 and 2, the support members 11, 12 do not contact each other and are in fact spaced apart by a considerable gap. There is no hint or suggestion to completely divert from this principle into the idea that the leaf springs 18 should NOT function as a cantilever beam and should not space the support members 11, 12 apart. Concerning Fig 5, this embodiment is described as incorporating the Fig 1 spring joint, so this confirms that also in Fig 5, the stack of leaf springs 18 is load-bearing in respect of axial loads and spans a gap between the support members 32, 34. Furthermore, in Fig 5, the cavity in component 32 is drawn considerably shorter than upwardly protruding part of the leaf springs 18. Hence, both the description and the drawing of Fig 5 supports that the cavity is shorter than the leaf springs 18.

Furthermore, the person of ordinary skill in the art would not seek to protect the flexible component from damage by modifying Fixel's design so that the cavity was made longer than the leaf springs 18, because Fixel has already solved the problem of protecting the leaf springs 18 in a different way. For example, in Fig 2, the exposed portion of the stack of leaf springs 18 is protected by interfitting hollow hemispherical members 20, 21. Hence, having already been presented with this alternative way of protecting the leaf springs 18, there is no need for the person of ordinary skill to design any further around a problem which has already been solved.

Therefore, without prejudice to their individual merits, Claims 6 and 7 are nonobvious over Fixel in view of Vitale, and Claims 24-26 and 28-29 are nonobvious over Fixel in view of Huebner, for at least the same reasons as set forth above for Claim 1.

New Claims 34 and 35

Independent claim 34 shares the novel and non-obvious features of claim 1 that the flexible component is free to move axially, laterally and rotationally within the cavity.

Independent claim 35 shares the novel and non-obvious feature of claim 1 that the cavity formed by the bores in the first and second components is longer than the flexible component.

Hence, claims 34 and 35 are also novel and non-obvious, for the same reasons as explained above with respect to claim 1

CONCLUSION

As explained above, amended claim 1 has at least two differentiating features not present in Fixel:

1. The flexible component being free to move laterally and rotationally within the cavity.
2. The cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity.

If Fixel's leaf springs were free to rotate laterally and rotationally within the cavity, the stack of leaf springs would become disordered and the leaf springs would become damaged. Hence, the person of ordinary skill in the art would never modify Fixel's device such that the leaf springs could move laterally and rotationally within the cavity.

Furthermore, the person of ordinary skill in the art would not modify Fixel such that the cavity was longer than the flexible component, because if he wished to improve the strength, he would use more springs or stronger springs, and if he wished to limit the damage to the springs and increase longevity, he would use the protective spherical cover of Fig 2. However, he would find no inspiration or motivation to completely redesign Fixel such that, against the core teachings of Fixel, the stack of leaf springs was no longer load-bearing, the cavity was formed longer than the springs, and the springs no longer

provided a cantilever beam bridge to transfer axial loads between the two support members. Hence, amended claim 1 is non-obvious over Fixel.

Accordingly, for at least the foregoing reasons, neither Fixel, Vitale or Huebner teach or suggest an implantable replacement joint wherein the cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity, and wherein the flexible component is free to move laterally and rotationally within the cavity., as recited in amended Claim 1. As Claims 2-6, 10-22, 24-26 and 28-29 are all dependent on Claim 1, these claims are also novel and non-obvious, at least by virtue of their dependencies.

In view of the foregoing amendments and remarks, it is respectfully submitted that the application, including Claims 1-6, 10-22, 24-26, 28-29 and 34-35, is in condition for allowance. An early notice of allowance is earnestly solicited.

Respectfully submitted,

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